REMARKS

Claims 1-19 are currently pending in this application. By this Amendment, claims 6, 13, and 16 have been amended. The amended claim set is provided herewith.

§ 112 Rejection of the Claims

Claim 13 has been rejected to as being indefinite under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 13 to recite a "porous material" instead of "Dacron mesh." Support for the amendment may be found in Paragraph [0058] of the Detailed Description in which the following is disclosed: "the hydrogel may be enclosed in a layer of porous material, such as Dacron mesh." Withdrawal of this rejection is respectfully requested.

§ 102 Rejection of the Claims

Claims 6-13 and 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Johnson (U.S. Patent No. 6,338,345). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Johnson et al. fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Claims 6-9

Independent claim 6 recites a system that includes a tubular instrument having a distal end and sized for introduction into a urethra, the distal end including a cavity. Claim 6 also requires a vacuum port to draw a portion of a urethral wall into the cavity, a needle to make a hole through the urethral wall in the portion of the urethral wall disposed in the cavity, and a pushing agent to push a bulking prosthesis through the tubular instrument and through the hole in the urethral wall. Johnson fails to teach or suggest the elements of independent claim 6.

In the Office Action, the Examiner acknowledged that Johnson does not teach using the device with the urethra wall. However, the Examiner asserted that the limitation of using the

device with the urethral wall is considered to be directed to the intended use of the device, and further asserted that the Johnson device is clearly capable of performing the intended use.

As amended, claim 6 requires a tubular instrument "sized for introduction into a urethra." Johnson discloses a delivery device that delivers a "bulking device below a tissue surface such as below the mucosa to treat gastroesophageal reflux disease."[1] Johnson teaches that cap 50 of FIG. 16 has "an outside diameter of about 0.6 inches"[2] and that the "outside diameter of the overtube [of FIG. 17] is about 0.7 inches."[3] The dimensions of the Johnson device are far too large to be introduced into a urethra, and Johnson does not describe the use of the device within a urethra.

Johnson does not describe the delivery of bulking devices anywhere other than in the esophagus of a patient. In addition, there is no suggestion of modifying the scale of the Johnson device in order to allow the Johnson device to be introduced into a urethra. For at least these reasons, Johnson fails to teach or suggest a tubular instrument sized for introduction into a urethra, as set forth in claim 6.

Dependent claims 7-9 are allowable for at least the reasons put forth with respect to independent claim 6, from which they depend.

Johnson fails to disclose each and every limitation set forth in claims 6-9, as amended. For at least these reasons, the Johnson reference would not support a prima facie case of anticipation of Applicant's claims 6-9 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

Claims 10-13 and 15

Independent claim 10 defines a device comprising a bulking prosthesis in the shape of a partial cylinder having an inner radius, wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water. Claim 10 also requires that the inner radius of the partial cylinder is sized to conform to close the urethra of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the urethra of the patient and when the patient exercises voluntary control over an external urethral sphincter. Johnson fails to teach or suggest the elements of independent claim 10.

---

[1] Johnson et al., Abstract.
[2] Johnson et al., Col. 11, ll. 62-63.
[3] Johnson et al., Col. 13, ll. 60-61.

In the Office Action, the Examiner stated that Johnson teaches that the bulking prosthesis can take on a wide variety of shapes and sizes and that these optimal dimensions are patient specific and can be determined through routine experimentation of one skilled in the art. Yet, the Examiner did not identify any teaching within Johnson that would anticipate the use of a bulking prosthesis in the shape of a partial cylinder. Hence, a partial cylinder shape is not among the "wide variety of shapes and sizes" contemplated by Johnson. Therefore, Johnson cannot support a prima facie case of anticipation.

The Examiner acknowledged that Johnson does not specifically teach using the device with the urethral wall. However, the Examiner considered the urethral limitations to be intended use of the device, and asserted that the Johnson device is clearly capable of performing the intended use. Applicant disagrees with the conclusions of the Examiner.

First, the Examiner's dismissal of certain limitations as intended use is incorrect. Per claim 10, the shape of bulking prosthesis is a partial cylinder having an inner radius that is sized to conform to close the urethra when the patient exercises voluntary control over an external urethral sphincter. These shape and dimension limitations in claim 10 are not a matter of mere intended use. Rather, they represent clear structural limitations that cannot be disregarded in considering patentability of the claimed invention.

Second, notwithstanding the explicit structural limitations discussed above, the Examiner's characterization of the Johnson device as being capable of use for urethral applications is mistaken. Again, the size of the delivery device described by Johnson far exceeds the size range appropriate for urethral insertion. The Johnson device is configured for the much larger space accommodated by the esophagus. Accordingly, the size of the Johnson delivery device is consistent with the point that the bulking agent delivered by Johnson does not have a shape and size to conform to close the urethra, as set forth in claim 10.

With further reference to the bulking prosthesis limitation, Applicant notes that Johnson describes an esophageal bulking device 16 comprising "an oblong, cylindrical, elliptical, toric or pillow shape."[4] In addition, FIGS. 3, 4, 5 and 6 show bulking devices with generally circular or oval cross-sectional configurations. However, Johnson does not contemplate any bulking prosthesis in the shape of a partial cylinder having an inner radius, as defined in claim 10.

[4] Johnson et al., Col. 6, ll. 50-52.

Johnson also fails to provide any suggestion of a similar shape or a device configured to deploy such a bulking prosthesis.

In addition to lacking a suggestion of a partial cylinder shape, Johnson does not teach or suggest a bulking prosthesis having an inner radius of such a partial cylinder that is sized to conform to close the urethra of a patient. Johnson describes bulking devices in which "a larger transverse cross-sectional area will produce a higher closing pressure."[5] However, Johnson fails to describe or suggest any bulking prosthesis having a partial cylinder shape defined an inner radius. Further, Johnson fails to teach a bulking prosthesis having an inner radius of the partial cylinder that is sized to conform to close the urethra of a patient.

Dependent claims 11-13 and 15 are allowable for at least the reasons put forth with respect to independent claim 10, from which they depend.

Johnson fails to disclose each and every limitation set forth in claims 10-13 and 15. For at least these reasons, Johnson does not support a prima facie case of anticipation of Applicant's claims 6-9 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

§ 103 Rejections of the Claims

Claims 1-5 and 16-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson et al. in view of Goupil et al. (U.S. Patent No. 6,652,883). Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Durgin (U.S. Patent No. 6,591,838). Applicant respectfully traverses the rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Neither Johnson, nor the Goupil reference, provides any teaching that would have suggested a reason for modification of the Johnson device to conform to the requirements of Applicant's claims. To establish obviousness, there must be an apparent reason why one of ordinary skill in the art would have been motivated to make a modification or combination to arrive at the claimed invention. KSR Int'l Co. v. Teleflex, Inc., No. 04-1350, Slip op. at 14. (April 30, 2007).

[5] Johnson et al., Col. 6, ll. 45-47.

Consistent with KSR, the Federal Circuit has stated that there must be "some rationale, articulation, or reasoned basis" to support the legal conclusion of obviousness." Alza Corp. v. Mylan Laboratories, 80 USPQ2d 1001, 1005 (Fed. Cir. 2006) (citing In re Kahn, 78 USPQ2d 1329 (Fed. Cir. 2006)). The reason for modification need not conform to the particular motivation or objective of the patent applicant. KSR, Slip op. at 16. However, there still must be some need or problem known in the art that would provide a reason for combining elements in the manner claimed. Id.

There is no rational reason to undertake the requisite modification of the Johnson device to conform to the claimed invention. Johnson focuses on bulking of the esophageal wall to address gastrointenstinal reflux disease (GERD). Johnson makes no mention of application of bulking to other body lumens, such as the urethra, nor the necessary modifications to a delivery device or technique to permit introduction into the urethra. Goupil describes urethral bulking, but makes no mention of any particular delivery device or technique similar to those contemplated by Johnson for implantation of bulking agents.

Claims 1-5

Independent claim 1 requires a method for treating urinary incontinence comprising applying vacuum pressure to an instrument proximate to a urethral wall to draw a portion of the urethral wall into a cavity in the instrument, forming a hole in the portion of the urethral wall disposed in the cavity, and implanting a bulking prosthesis through the hole proximate to a urethral sphincter.

In the Office Action, the Examiner noted that Johnson fails to teach using the bulking prosthesis for treating urinary incontinence. The Examiner pointed to Goupil, however, as teaching that it is well known to use a bulking material to treat a variety of problems including GERD and urinary incontinence. On this basis, the Examiner stated that modifying Johnson such that the bulking device is used to treat urinary incontinence would have been obvious in view of the Goupil device.

Applicant disagrees with the Examiner's obviousness rejection. There would have been no apparent reason for one of ordinary skill in the art to combine the references of Johnson and Goupil. Johnson describes a particular delivery device and technique for controllably delivering

a prosthetic bulking device to treat gastroesophageal reflux disease. Goupil teaches a variety of compositions for tissue bulking and coating. However, there is no suggestion in Goupil that would have suggested reducing the size of the Johnson device and adapting the device for application to urinary sphincter bulking. Goupil focuses on particular compositions for bulking articles, but describes no delivery devices or techniques similar to those of Johnson. Moreover, as explained below, the devices and techniques described by Johnson would not even be appropriate for delivery of the majority of the bulking materials described by Goupil.

The Johnson delivery device includes a deployment device 90 that has "cavity 102 for receiving bulking media 106."[6] For deployment, "inner element 98 causes the plunger 104 to distally deploy the bulking media 106."[7] In this manner, Johnson only describes one cavity or lumen within outer tube 100 to deploy bulking media 106. Goupil, on the other hand, discloses compositions that rely on crosslinked macromers to "form hydrogels having many properties advantageous for use as agents to bulk and coat tissues." Goupil describes the use of a catheter, syringe or spray device for delivery of bulking materials.[8] However, Goupil indicates that "a multi-lumen catheter is used to deliver the composition to the intended site of administration."[9] In particular, for compositions including different components, the delivery methods and devices described by Goupil require a multi-lumen catheter to deliver the compositions at the delivery site.

Goupil describes preformed bulking and sealing articles[10], but appears to provide no mention of techniques for delivery of a preformed article other than by catheter.[11] In Goupil, there is no suggestion, whatsoever, of the desirability of applying vacuum pressure to a urethral wall. Accordingly, one of ordinary skill in the art in view of Johnson and Goupil would have found no teaching that would have suggested modification of the technique described by Johnson to deliver bulking prostheses proximate to the urethral sphincter, as claimed. The desirability of such a modification would have been apparent only upon access to Applicant's own disclosure, which is impermissible.

---

[6] Johnson et al., Col. 15, ll. 7-8.
[7] Johnson et al., Col. 15, ll. 11-13.
[8] Goupil, Col. 16, ll 40-43.
[9] Goupil et al., Col. 16, ll. 43-44.
[10] Goupil et al., Col. 13, ll. 36-43.
[11] Goupil et al., Col. 16, ll. 30-37 and 40-43.

Dependent claims 2-5 are allowable for at least the reasons put forth with respect to independent claim 1, from which they depend.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-5 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Claims 16-19

Independent claim 16, as amended, requires a method for treating urinary incontinence comprising applying vacuum pressure to tissue proximate the urethral sphincter, and implanting a bulking prosthesis in the portion of the tissue proximate to the urethral sphincter. The bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, and the bulking prosthesis includes a long dimension of at least two millimeters in the enlarged state.

For substantially the reasons stated above with respect to claim 1-5, it would not have been obvious to modify the delivery techniques describe by Johnson to implant a bulking prosthesis in tissue proximate a urethral sphincter to treat urinary incontinence. Again, there would have been no apparent reason to modify a device designed for use in the esophagus to deliver bulking agents for bulking of the urethral sphincter.

Dependent claims 17-19 are allowable for at least the reasons put forth with respect to independent claim 16, from which they depend.

For at least these reasons, the prior art references fail to support a prima facie case for non-patentability of Applicant's claims 17-19 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Claim 14

Dependent claim 14 is allowable for at least the reasons put forth with respect to independent claim 10, from which it depends. Durgin provides no teaching sufficient to overcome the basic deficiencies evident in the Johnson reference.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 5-17-07

By: 

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Steven J. Shumaker
Reg. No.: 36,275